

***Remarks***

This Amendment is in response to the Office Action dated **January 24, 2008**.

Applicant has canceled claims 1-32 without prejudice as these claims are drawn to a non-elected invention. Applicant reserves the right to prosecute these claims in a divisional or continuing application.

***Claim Rejections***

***35 U.S.C. §112***

Claims 37-38 and 40-43 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is asserted in the Office Action that “[c]laims 37-38 recite the limitation “ultraviolet crosslinkable polymer” in line 1. There is insufficient antecedent basis for this limitation in the claim.”

Applicants have amended claims 37-38.

It is further asserted in the Office Action that “[c]laims 40-43 recites the limitation “at least one hydrophilic polymer” in line 1. There is insufficient antecedent basis for this limitation in the claim.”

Applicants have amended claims 40-43.

Applicants respectfully request withdrawal of the rejection of claims 37-38 and 40-43 under 35 U.S.C. §112, second paragraph.

**35 U.S.C. §103(a)**

Claims 33-35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Buscemi et al. (US 5693034) in view of Ichimura (US 4272620). It is asserted in the Office Action that:

Buscemi et al. discloses a lubricous polymer network used as a coating for a medical device which exhibits great lubricity when wet (see abstract). The polymer network comprises a vinyl polymer and an uncrosslinked hydrogel retained within the vinyl polymer (see col. 1, lines 51-59). The network is formed into a coating by applying a mixture of an uncrosslinked hydrogel, a vinyl prepolymer, and a free radical initiator in a solvent to activate (see col. 2, lines 22-30). The film is crosslinked by using the free radical initiators and the coating is exposed to heat or UV light for a short period to cure the coating (see col 3, lines 33-40) Buscemi et al., teaches that the advantage to using the vinyl polymer is its ability to adhere to a substrate (see col. 3, line 44-50).

Buscemi et al. fail to teach that the crosslinkable polymer is an oxygen insensitive non cationic mechanism as required by claim 33. However, it was well known to use such polymers when dealing with hydrophilic polymers as taught by Ichimura. Ichimura teaches a hydrophilic resin comprising polyvinyl alcohol polymeric backbone containing styrylpyridinium groups. The resin is highly sensitive and without the use of any sensitizer which is economically desirable because it only need a very small content of photosensitive group (see col. 6, lines 50-60).

Office Action, pages 3-4.

Applicant traverses the rejection.

Applicant submits that Buscemi et al. disclose:

A polymer network useful as a lubricous coating, the polymer network comprising a reaction product of a vinyl prepolymer and an uncrosslinked hydrogel retained within the reaction product such that the network exhibits greater lubricity when wet.

Abstract

Ichimura discloses:

A hydrophilic resin comprising a polyvinyl alcohol polymeric backbone and containing styrylpyridinium groups is a photosensitive resin. The photosensitive resin is prepared by reacting a styrylpyridinium salt containing a formyl or acetal group with a polyvinyl alcohol compound.

Abstract

It is asserted in the Office Action that "...it was well known to use such polymers when dealing with hydrophilic polymers as taught by Ichimura." This is incorrect.

Buscemi et al. disclose that a lubricious coating can be formed on a medical device by using a polymerized vinyl prepolymer to form a polymer network with an uncrosslinked hydrogel, the polymer network meaning that the two polymers are synthesized so that the polymer chains are intertwined with one another (Detailed Description, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs). The polymerized vinyl polymer is employed to secure the lubricious polymer to the medical device. See Summary of the Invention.

Ichimura, on the other hand, employs "[a] hydrophilic resin comprising a polyvinyl alcohol polymeric backbone and containing styrylpyridinium groups is a photosensitive resin..." Abstract. There is absolutely no suggestion that the hydrophilic resin comprising the alcohol polymeric backbone and containing styrylpyridinium groups be employed in combination with any other polymer to form a polymer network, much less a suggestion to combine it with a hydrophilic polymer to form a polymer network that imparts lubricity to the surface of a medical device. Therefore, the assertion in the Office Action that it was well known to use such polymers when dealing with hydrophilic polymers is not taught by Ichimura.

Furthermore, there is no suggestion by Buscemi et al. that styrylpyridinium substituted polyvinyl alcohols can be employed as a substitute for the vinyl prepolymers disclosed therein in order to successfully secure the uncrosslinked hydrogel to a medical device.

Consequently, a *prima facie* case of obviousness is not established with this combination because the combination fails to suggest a polyvinyl alcohol substituted polymer in combination with an uncrosslinked hydrogel for purposes of providing lubricity to the surface of a

medical device, nor does the combination provide any impetus to substitute the polyvinyl alcohol substituted polymer disclosed by Ichimura for the vinyl prepolymers disclosed by Buscemi et al. for purposes of forming a lubricious polymer network with an uncrosslinked hydrogel. The suggestion is simply not there.

This combination would only be made with the use of impermissible hindsight, by using Applicant's invention as a blueprint to select elements from the prior art.

As this court has stated, "virtually all [inventions] are combinations of old elements." Therefore, an examiner [or accused infringer] may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner [or accused infringer] to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention.

. . .

... To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.

*Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal Inc.*, 56 USPQ2D 1641, 1644 (Fed. Cir. 2000)(citing *In re Rouffet*, 149 F.3d 1350, 1357-58, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998).

Furthermore, even after KSR, there must be some recognizable benefit to making the substitution, without the use of hindsight.

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. MPEP 2142

Rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007).

Based on the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 33-35 under 35 U.S.C. §103(a) as being obvious over Buscemi et al. in view of Ichimura.

**CONCLUSION**

Claims 33-43 are pending in the application. The examiner failed to act on claim 36. Applicant has addressed each of the issues presented in the Office Action. Based on the foregoing, Applicant respectfully requests reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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